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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,194	01/08/2001	Graham P Belfield	3525-119	7361

23117 7590 04/18/2003
NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
1636	9

DATE MAILED: 04/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,194

Examiner

Gerald G Leffers Jr.

Applicant(s)

BELFIELD ET AL.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 46 is/are allowed.
- 6) ☒ Claim(s) 30,31,33-45 and 47-54 is/are rejected.
- 7) ☒ Claim(s) 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of an amendment, filed 1/29/03 as Paper No. 8, in which all of the then pending claims were cancelled (claims 1-29) and in which new claims were submitted (new claims 30-54). Claims 30-54 are now pending in the instant application.

Any rejection of record in the previous office action, mailed 8/13/02 as Paper No. 6, that is not addressed herein is withdrawn. This action is FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-31, 33-34, 36-43, 45, 47-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection that is necessitated by applicants' amendment of the claims in Paper No. 8.**

The claims are drawn towards an isolated and purified polynucleotide comprising SEQ ID NO: 4, or variants thereof, wherein the polynucleotide is operative as a promoter to express a coding sequence to which it is operatively linked. The variants have at least 90% identity along their entire length (although the specification never actually defines what the variants are supposed to have identity with). The claims also encompass vectors and host cells comprising the polynucleotide and methods of expressing a protein featuring the promoter activity of the

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polynucleotide. For many of the claims the level of promoter activity is controlled by the level of fermentable carbon source (e.g. glucose) and/or non-fermentable carbon source (ethanol) in the culture medium.

SEQ ID NO: 4 describes a 500-nucleotide sequence. Even for an embodiment featuring a 95% identity to SEQ ID NO: 4 along its entire length, there are a very large number of possible variants of SEQ ID NO: 4 that may or may not retain any promoter activity. For example, this encompasses any permutation of SEQ ID NO: 4 that has up to 25 different nucleotide changes arrayed in any manner over the 500 nucleotide range of SEQ ID NO: 4. Thus, the claims are broad genus claims encompassing a large number of fragments that must retain promoter activity. The size of the genus is further compounded by the functional limitation in at least some of the claims that the promoter must be responsive to fermentable and non-fermentable carbon sources in culture media.

SEQ ID NO: 4 is 500 nucleotides in length and describes a sequences that is found at the 3' end of the yeast open reading frame YOL110W and extends to the beginning of the YOL109W (ZEO1) reading frame (Figure 32 of the instant specification). The specification describes the cloning of SEQ ID NO: 4 into an expression vector with a reporter polypeptide (luciferase) to demonstrate that the sequence described by SEQ ID NO: 4 possesses promoter activity and that the promoter activity is responsive to both glucose and ethanol in culture media (Table 7). No description is provided in the specification of any fragment of SEQ ID NO: 4 of any length that retains promoter activity. No description is provided in the specification of any sequence within SEQ ID NO: 4 that resembles a known transcription factor binding sequence (e.g. GAL4, etc.). The specification provides no guidance with regard to which fragments within

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SEQ ID NO: 4 might be essential for response to fermentable or non-fermentable carbon sources within the culture media.

The prior art does not offset the deficiencies of the instant specification with regard to description of the claimed invention. Promoter sequences comprising SEQ ID NO: 4 do not appear to have been described in the prior art. While one of skill in the art might be able to identify sequences within SEQ ID NO: 4 that possess some homology to binding sites for known transcription factors, there may well be other unknown transcription factors required for even the basal level of promoter activity associated with SEQ ID NO: 4, much less glucose- or ethanol-responsive activities. Again, there is no description in the art of record for regulatory sequences to express ZEO1 in yeast.

Given the great number of possible variants of SEQ ID NO: 4 encompassed by the rejected claims and the limitation that the fragments must retain at least some functional activity, and given the lack of a structural/functional basis provided by the instant specification or prior art for one of skill in the art to envision those embodiments that actually do retain promoter activity, the skilled artisan would not have been able to envision a sufficient number of the claimed embodiments to describe the broadly claimed genus. Therefore, the skilled artisan would have reasonably concluded that applicants were not in possession of the claimed invention.

Response to Arguments

Applicant's arguments filed in Paper No. 8 have been fully considered but they are not persuasive. The response essentially argues the amendment of the claims has obviated the rejection. However, because of the limitation of variants with as much as 10% deviation from

the sequence described in SEQ ID NO: 4 and the lack of description in the prior art or instant specification as to what portions of SEQ ID NO: 4 are required for the observed promoter activity, the rejections for lack of written description remain. Those embodiments directed to exclusively to SEQ ID NO: 4 have been adequately described and appear to be free of the art.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30, 33-36-43, 45-45, 47-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **These are new rejections, necessitated by applicants' amendment of the claims in Paper No. 8.**

Claims 30-54 recite the limitation of "variants thereof having along their entire length a sequence identity of 90% [95%]". The specification does not make clear as to what the "variants" of SEQ ID NO: 4 are to be compared, one another or to SEQ ID NO: 4. It would be remedial to amend the claim language to clearly indicate what has identity to what in the rejected claims. Claims 32 and 35 are not rejected because the claimed invention is limited to SEQ ID NO: 4.

Claim 35 is vague and indefinite in that it is not clear whether the recited plasmids are supposed to have an additional promoter nucleotide that is supposed to satisfy the limitations of claim 30, or whether the claimed vector is only limited to SEQ ID NO: 4.

Conclusion

Claims 30-31, 33-45, 47-54 are rejected. Claim 46 is allowed. Claim 32 is objected to as being dependent upon a rejected claim, but would be allowable if rewritten in independent form.

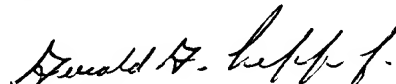
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Gerald G Leffers Jr.
Examiner
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